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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/583,860	05/21/2007	Takashi Nishimura	3691-0133PUS1	8593

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EXAMINER	
CHEN, SHIN LIN	

ART UNIT	PAPER NUMBER
1632	

NOTIFICATION DATE	DELIVERY MODE
06/01/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 10/583,860	**Applicant(s)** NISHIMURA ET AL.
	Examiner SHIN LIN CHEN	**Art Unit** 1632

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 12 May 2011 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires *4* months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: *None*.
   Claim(s) objected to: *None*.
   Claim(s) rejected: *1,3-5,7-9,11-13,15-17 and 22*.
   Claim(s) withdrawn from consideration: *6,14 and 18-21*.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

/Shin-Lin Chen/
Primary Examiner
Art Unit: 1632

Continuation of 11. does NOT place the application in condition for allowance because: Applicants argue that Tc1 and Th1 cells are different from each other. Kessels describes transducing a virus antigen-specific, class I-restricted T cell receptor gene into killer T cells, or into whole spleen cells containing helper T cells but there is a lack of induction of helper T1 cells. Kessels's results suggest that co-application of antigen-specific class I and class II TCR is essential, therefore, Kessels teaches away from the instant invention, which only requires introduction of class I-restricted TCR into helper T cells to expand antigen specific helper T1 cells. Fujio describes introduction of Class II-restricted TCR into TG40 cells (derived from a helper T cell and a cancer cell) to obtain a tumor antigen specific CD4+ cells. Tsuji teaches a class I-restricted TCR gene is introduced into killer T cells to induce functional killer T cells, one of ordinary skill would not predict that functional helper T1 cells could have been prepared by transducing helper T cells with a class I-restricted TCR gene. Nishimura does not suggest induction of tumor antigen specific helper T1 cells. Fujio, Tsuji and Nishimura fail to remedy the deficiency of Kessels (Remarks, p. 2-7). This is not found persuasive because of the reasons of record. The claims read on a process of preparing cells for cell therapy comprising inducing helper T1 cells that have a nonspecific antitumor activity from leukocytes isolated from a patient, and imparting antigen specificity to the helper T1 cells by transducing the helper T1 cells with a T cell receptor gene that recognizes a cancer-associated antigen, wherein the TCR gene is a MHC class I-restricted or class II-restricted T cell receptor gene. Either class I or class II-restricted TCR can be introduced to Th1 cells to impart antigen specificity and Kessel teaches introduction of class I-restricted TCR into whole spleen cells containing helper T cells and Fujio teaches introduction of class II-restricted TCR into TG40 cells derived from helper T cells. Therefore, it would be obvious for one of ordinary skill in the art to practice the claimed invention in view of the teachings of Kessels, Fujio, Tsuji and Nishimura. Only claim 3 is specifically limited to introducing MHC class I-restricted TCR into helper T1 cells. However, it should be noted that the claims read on a process of preparing cells for cell therapy, and imparting antigen specificity to the Th1 cells and Tc1 cells only requires transducing the Th1 cells and Tc1 cells with a TCR gene that recognizes a cancer-associated antigen (see claims 1 and 9). Whether the Th1 cells or Tc1 cells are induced or activated or not appears to be irrelevant in the instant invention. Thus, the claims remain rejected for the reasons of record and the reasons set forth above.